UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	**1:18-cv-04361-AKH**
This Document Relates To: **All Actions**	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL THIRD PARTIES LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC. TO PRODUCE DOCUMENTS RESPONSIVE TO RULE 45 SUBPOENA

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I. INTRODUCTION

Plaintiffs respectfully ask the Court to compel third-parties Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") to produce documents described with specificity in response to the subpoena *duces tecum* served by Plaintiffs nearly a year and a half ago in February 2019.[1] Ex. 1, February 2019 Subpoena, (hereinafter the "Subpoena").[2] Over the last fourteen months, Plaintiffs have exchanged more than twenty letters, dozens of emails, and held five teleconferences with Lupin regarding the subpoena. The information sought is directly relevant to Plaintiffs' proof of causation and damages in this case: that but for Novartis's anticompetitive agreement with Par to delay generic entry, Lupin, another generic competitor that actually entered the market, had the capacity, capability and economic incentive to enter the market earlier absent the Novartis/Par reverse payment agreement.

Lupin has not claimed—and indeed, cannot claim—that the documents sought in this motion are not available or are too burdensome to produce. To the contrary, Lupin previously acknowledged that the documents sought by Plaintiffs are both responsive and available. Specifically, in April 2019, Lupin acknowledged the responsiveness of the following types of documents:

- "launch timelines, projections, and forecasts, schedules, launch updates and launch team meeting minutes, manufacturing forecasts, records of exhibit batches, scale up batches, validation batches, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same" in response to Request No. 4 of the

[1] "Plaintiffs" includes Direct Purchaser Plaintiffs, End-Payor Plaintiffs, and Retailer Plaintiffs Walgreen Co., The Kroger Co., and H-E-B, L.P., CVS Pharmacy, Inc., Rite Aid Corporation, and Rite Aid Hdqtrs. Corp.

[2] Exhibits referenced herein are attached to the Declaration of Dan Chiorean, filed contemporaneously herewith.

Subpoena; and

- "documents sufficient to show any regulatory, legal, technical, manufacturing, or other issues or reasons why Lupin could or could not or would or would not commercially launch generic Exforge prior to [March 30, 2015]" in response to Request No. 5 of the Subpoena.[3]

Lupin has failed to produce the categories of documents it identified as responsive more than a year ago. Now, on April 17, 2020, Lupin claimed that its paltry production fulfills its obligations pursuant to the Subpoena and refuses to produce any more documents.[4] Accordingly, Plaintiffs respectfully request that the Court intervene and order the production of the below-listed documents responsive to Subpoena Request Nos. 4, and 5 within forty-five (45) days[5]:

1. Process validation[6] reports for all four strengths of Lupin's Generic Exforge.
2. Process validation batch manufacturing records for all four strengths of Lupin's Generic Exforge.
3. New Product Launch Meeting minutes for Lupin's Generic Exforge from the date launch planning began until April 1, 2015.
4. Documents sufficient to show the amount of generic Exforge finished product inventory that Lupin had on hand at the time of launch on March 30, 2015 and the date Lupin began to manufacture that inventory.
5. Lupin's generic Exforge launch timeline(s) showing planned and completed tasks in preparation for launch starting on January 1, 2011 and ending on April 1, 2015.
6. Documents sufficient to show when Lupin ordered the required active pharmaceutical

[3] Ex. 2, April 19, 2019 Letter Correspondence from Lupin to Plaintiffs, at 1.

[4] Ex. 3, April 17, 2020 Letter Correspondence from Lupin to Plaintiffs.

[5] Plaintiffs realize that ongoing business disruptions due to the COVID-19 pandemic may impose some delays. We do note that the *Namenda* court ordered Lupin to produce similar documents within just sixteen (16) days and Lupin complied. *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-CIV-7488-CMJCF, 2017 WL 3822883, at *10 (S.D.N.Y. Aug. 30, 2017) ("Namenda II") ("Lupin Pharmaceuticals shall produce the requested documents within its possession, custody, or control on or before September 15, 2017.").

[6] Process validation "is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product." *See* FDA, *Guidance for Industry, Process Validation: General Principles and Practices*, January 2011, *available at* https://www.fda.gov/files/drugs/published/Process-Validation--General-Principles-and-Practices.pdf.

ingredients ("API"), other excipients, and packaging intended for use in its first commercial batches of generic Exforge manufactured for its March 30, 2015 launch, and in what quantities.

7. Documents between January 1, 2011 and March 30, 2015 sufficient to show the extent to which, if at all, Lupin considered and took steps towards launching generic Exforge earlier than March 30, 2015. This may include launch timelines, purchases of API or other excipients, manufacturing of process validation batches, or internal correspondence indicating a proposed launch date.

8. Documents sufficient to show whether Lupin encountered any difficulties in manufacturing its commercial batches of generic Exforge in preparation for its March 30, 2015 launch.

9. Documents sufficient to show when Lupin purchased or made available the equipment used in the manufacturing of generic Exforge commercial batches in advance of its March 30, 2015 launch.

These documents will contain information regarding, *inter alia*, (1) the date process validation began, (2) the date process validation ended (and whether the first attempt at process validation was successful), (3) the date Lupin ordered API in preparation for launch, (4) the date Lupin received its API, (5) the date Lupin began manufacturing scale-up batches in advance of its March 30, 2015 launch, (6) the date Lupin completed manufacture of scale-up batches, (7) how many commercial batches (and what was the batch size) Lupin had successfully manufactured prior to Mach 30, 2015, and (8) whether Lupin experienced any difficulty in manufacturing scale-up batches. As explained below, this information is relevant to liability, causation, and damages.

Moreover, as explained in Section V, *infra*, Lupin cannot seriously contend that producing these documents is unduly burdensome (and Lupin has articulated no such burden) because: (1) Plaintiffs' Subpoena was narrowly tailored; (2) Plaintiffs significantly reduced the scope of the Subpoena through negotiations with experienced counsel representing Lupin; (3) Lupin has already acknowledged the responsiveness of these documents without raising any significant burden claims; (4) Lupin is a large, sophisticated pharmaceutical company regularly engaged in drug development, related litigation, and third party subpoenas, and Lupin is not lacking in

resources and knowledge; (5) Lupin operates in a highly regulated industry and regulations mandate that the bulk of the documents Plaintiffs seek are properly and accurately catalogued, stored, and maintained in case they are requested by FDA inspection personnel – thus, they are easily retrievable, and (6) Lupin was previously ordered by another court in this District to produce substantially similar documents pursuant to a subpoena from plaintiffs in another delayed generic entry antitrust case (and Lupin did so).

Plaintiffs therefore respectfully request that this Court grant Plaintiffs' Motion to Compel and order Lupin to produce the documents set forth above. Plaintiffs also request oral argument on this Motion[7] because Plaintiffs believe the Court would benefit from a further explanation of the relevance of these specific documents, as well as their utility to Plaintiffs' subject matter experts.

II. FACTUAL BACKGROUND

Plaintiffs allege that Defendants Par and Novartis unlawfully monopolized the amlodipine/valsartan market in violation of federal and state antitrust law by entering into an anticompetitive "pay-for-delay" agreement in December 2011, disguised as a license agreement between Novartis and Par.[8] Plaintiffs further allege that Defendants' agreement had the purpose and effect of improperly delaying market entry of less expensive generic versions of Exforge by Par and other generic manufacturers including Lupin, causing Plaintiffs to pay more for amlodipine/valsartan tablets than they would have but for Defendants' unlawful conduct.[9]

More specifically, and particularly relevant here, Plaintiffs allege that had Par not entered into the "pay-for-delay" agreement with Novartis, it would have come to market with its less

[7] Plaintiffs make this request in accordance with the Court's procedures as outlined in the latest Southern District of New York Court Operations announcement in response to COVID-19.

[8] *See* Op. and Order Granting Defs.' Partial Mot. to Dismiss, ECF No. 193 at 2.

[9] ECF No. 193 at 5.

expensive generic version of Exforge earlier than it actually did. This, in turn, would have allowed other generic manufacturers of Exforge, such as Lupin, to also enter the market earlier. As the first generic manufacturer to challenge Novartis' patents for Exforge, Par was eligible for a 180-day exclusivity period free of competition from other generic manufacturers of Exforge.[10] That 180-day period began to run once Par entered the market with its own generic Exforge on September 30, 2014, *i.e.*, the agreed-upon entry date with Novartis.[11] Thus, absent the "pay-for-delay" agreement between Par and Novartis, Par would have entered the market earlier than September 30, 2014, causing its 180-day exclusivity period to end earlier, and in turn other generic companies such as Lupin would also have entered the market earlier than they actually did.[12] As a matter of economics, but for the anticompetitive agreement between Novartis and Par, the more generic companies that would have entered the market with generic Exforge earlier, the lower the prices would have been for amlodipine/valsartan tablets.

III. PROCEDURAL BACKGROUND

Here, Plaintiffs served Lupin with the operative Subpoena on February 11, 2019.[13] The Subpoena sought a range of documents, including, *inter alia*: (i) documents concerning plans for launching generic Exforge or Exforge HCT (Subpoena Request No. 4); and (ii) documents concerning "any regulatory, legal, technical, manufacturing, or other issues or reasons why [Lupin] or any other Generic Exforge ANDA filer could or could not or would or would not commercially

[10] No regulation, however, prevents the brand company from selling a generic version of its own branded drug during this period.

[11] ECF No. 193 at 5.

[12] Lupin received final approval for and launched its generic Exforge product on March 30, 2015 upon expiration of Par's 180-day exclusivity period after its delayed launch.

[13] Ex. 1, Feb. 11, 2019 Direct Purchaser Pls.', End-Payor Pls.' and Walgreen Pls.' Notice of Service of Subpoena Duces Tecum to Lupin Pharm., Inc. and Lupin Ltd. (the "Subpoena").

launch a Generic version of Exforge prior to September 30, 2014" (Subpoena Request No. 5).

Lupin served Responses and Objections on February 25, 2019,[14] and negotiations with Lupin after that date have been extensive.[15] In response to arguments made by counsel for Lupin and mindful of Lupin's position as a third party, Plaintiffs agreed to narrow the scope of the Subpoena.

Over the course of subsequent written correspondence and telephonic meet-and-confers, Lupin and Plaintiffs agreed on the scope of production pursuant to Request Nos. 4 and 5. During negotiations, Lupin confirmed its express understanding of the nature of the documents sought by the Subpoena and never claimed the documents were not available or too burdensome to produce:

> In addition to [Lupin's New Product Launch] meeting minutes, Plaintiffs are also demanding launch timelines, projections, and forecasts, schedules, launch updates and launch team meeting minutes, manufacturing forecasts, records of exhibit batches, scale up batches, validation batches, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same. In response to Request No. 5, Plaintiffs are demanding documents sufficient to show any regulatory, legal, technical, manufacturing, or other issues or reasons why Lupin could or could not or would or would not commercially launch generic Exforge prior to September 30, 2014.[16] . . . As you are aware, the additional documents Plaintiffs are demanding in response to Request Nos. 4 and 5 are the same types of documents that Plaintiffs sought from Lupin Pharmaceuticals, Inc. in response to a third-party subpoena issued in *In re Namenda Direct Purchaser Antitrust Litigation.*

Ex. 2 April 19, 2019 Correspondence from Lupin to Plaintiffs, at 1-2.

Lupin has not produced the vast majority of documents it acknowledged to be responsive

[14] *See generally* Ex. 4, Objections by Lupin Pharm., Inc. and Lupin Ltd. to February 2019 Subpoena.

[15] Counsel for Plaintiffs exchanged letters or e-mail with counsel for Lupin on more than twenty occasions: (1) 12/5/2018; (2) 2/11/2019; (3) 2/25/2019; (4) 4/3/2019; (5) 4/19/2019; (6) 4/26/2019; (7) 6/14/2019; (8) 6/26/2019; (9) 7/16/2019; (10) 7/22/2019; (11) 8/5/2019; (12) 8/13/2019; (13) 9/25/2019; (14) 10/8/2019; (15) 12/4/2019; (16) 1/13/2020; (17) 2/3/2020; (18) 2/6/2020; (19) 2/28/2020; (20) 4/10/2020; and (21) 4/17/2020. Plaintiffs' counsel Dan Chiorean has conducted telephonic meet-and-confers with Lupin's counsel on at least five occasions: (1) 2/4/2019; (2) 3/11/2019; (3) 3/29/2019; (4) 5/22/2019; and (5) 1/29/2020.

[16] As Plaintiffs explained to Lupin, this date should be March 30, 2015 – the day Lupin began commercial marketing of its generic Exforge product.

to the Subpoena other than the process validation report for one of the four strengths of its generic Exforge HCTZ product, but none for generic Exforge.[17] While Lupin's entire production is comprised of 1,111 documents, only twenty-four (24) of those, produced in February 2020, are documents arguably responsive to Request Nos. 4 and 5, and that production is deficient. Of the 24 documents, nine are duplicates, and the documents do not address eight of the nine categories in Section I, *supra*.[18] On April 10, 2020, Plaintiffs wrote to inform Lupin that is production was still deficient. In response, on April 17, 2020, Lupin stated it need not produce any more documents because it has "fully complied with Plaintiffs' Subpoenas" by having produced its "regulatory ANDA file" and its "New Product Launch meeting minutes."[19]

First, Lupin has not produced its New Product Launch meeting minutes despite offering to do so fourteen months ago.[20] Second, even if Lupin had produced the meeting minutes, as Plaintiffs explained to Lupin in March *2019*, those meeting minutes would not suffice to satisfy Request Nos. 4 and 5 because they would not reflect the additional information sought in those Requests.[21]

[17] This is despite the fact that, to aid Lupin, Plaintiffs named the process validation reports and process validation batch numbers required by their exact alphanumeric identifier used by Lupin. *See* Ex. 11, Jan. 13, 2020 Correspondence from Plaintiffs to Lupin, at 2 ("Among the documents in its production, Lupin must also include the following process validation reports: VR-15-024-00, VR-15-025-00, VR-15-034-00, and VR-15-035-00 … [and] batch manufacturing records for the following process validation batches, by strength: G501264, G501404, G501405, G501427, G501428, G501429, G501406, G501407, G501408, G501431, G501430, G501432"). Moreover, Lupin's production of its Exforge HCTZ Process Validation Report confirms that its process validation reports are readily accessible.

[18] For example, Lupin's production contains several exact copies of one-page "fact sheets" about its generic Exforge product, three exact copies of the same fact sheet for its generic Exforge HCTZ product, and a few production planning inventory ("PPIC") forecasts from 2011 and 2012, two of which are identical copies.

[19] *See* Ex. 3, Apr. 17, 2020 Letter from Lupin to D. Chiorean, at 1.

[20] See Ex. 12, Mar. 29, 2019 email correspondence from Lupin counsel to D. Chiorean, at 1 (Lupin is "willing to produce…In response to request No. 4 minutes from Lupin's New Product Launch meetings…").

[21] *See* Ex. 13, Apr. 3, 2019 Correspondence from Pls. to Lupin, at 2-3 (summarizing a March 29, 2019 teleconference); Ex. 12, at 1 March 29, 2019 email from Lupin counsel to D. Chiorean (sent ahead of teleconference outlining what Lupin was offering to produce). *See also* Section V, *infra*.

IV. LEGAL STANDARD

Motions to compel a subpoena are "entrusted to the sound discretion of the district court." *In re Fitch, Inc.*, 330 F.3d 104, 108 (2d Cir. 2003) (citing *United States v. Sanders*, 211 F.3d 711, 720 (2d Cir. 2000)); *accord In re World Trade Ctr. Disaster Site Litig.*, No. 05-cv-9141, 2009 WL 4722250, at *2 (S.D.N.Y. Dec. 9, 2009) (Hellerstein, J.) (citing *In re Fitch*, 330 F.3d at 108).

The issuing party "must demonstrate that the information sought is relevant and material to the allegations and claims at issue in the proceedings." *Bridgeport Music, Inc. v. UMG Recordings, Inc.*, No. 05-cv-6430, 2007 WL 4410405, at *3 (S.D.N.Y. Dec. 17, 2007) (internal quotation omitted). "The relevance standards set out in Federal Rule of Civil Procedure 26(b)(1) apply to discovery sought from non-parties," which provides that

> Parties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Mackey v. IDT Energy, Inc., No. 19 MISC. 29 (PAE), 2019 WL 2004280, at *3 (S.D.N.Y. May 7, 2019) (citing *Citizens Union of City of N.Y. v. Attorney General of N.Y.*, 269 F. Supp. 3d 124, 139 (S.D.N.Y. 2017) and Fed. R. Civ. P. 26(b)(1)).

If raised, the non-party bears the burden of demonstrating that compliance with the subpoena would be unduly burdensome. *See Bridgeport Music, Inc.*, 2007 WL 4410405, at *1-2; *Mackey*, 2019 WL 2004280, at *3. To determine whether a document subpoena imposes an undue burden, a court should examine "such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described[,] and the burden imposed." *MacNamara v. City of New York*, No. 04-civ-9612, 2006 WL 3298911, at *15 (S.D.N.Y. Nov. 13, 2006) (quoting *Travelers Indemnity Co.*

v. Metropolitan Life Ins. Co., 228 F.R.D. 111, 113 (D. Conn. 2005)).

"The trial court has broad discretion to determine whether a subpoena imposes an undue burden." *Mackey*, 2019 WL 2004280, at *3 (citing *Jones v. Hirschfeld*, 219 F.R.D. 71, 74 (S.D.N.Y. 2003)). While courts give special consideration to the burden of third parties when responding to subpoenas, discovery cannot be denied because there is some burden on the non-party. *Bridgeport Music, Inc.*, 2007 WL 4410405, at *3 (granting motion to compel non-party compliance with subpoena because "the documents are relevant and the burden, while not insignificant, is not so great as to justify quashing the subpoena…"); *see MacNamara*, 2006 WL 3298911, at *15 (denying motion to quash despite a burden when the requested documents are relevant and the request narrowly construed); *see also Bulkmatic Transp. Co. v. Pappas*, No. 99-civ-12070, 2001 WL 504839, at *2 (S.D.N.Y. May 11, 2001) (granting a motion to compel without consideration of burden raised by non-party in light of their "continued non-compliance with [a] subpoena").

V. ARGUMENT

Plaintiffs seek Court intervention because despite Lupin's agreement more than a year ago that the documents responsive to Requests Nos. 4 and 5 are relevant, Lupin has still not produced the documents sought by this Motion.

Specifically, Plaintiffs seek the following documents responsive to Subpoena Request Nos. 4 and 5:[22]

1. Process validation reports for all four strengths of Lupin's Generic Exforge.
2. Process validation batch manufacturing records for all four strengths of Lupin's Generic Exforge.
3. New Product Launch Meeting minutes for Lupin's Generic Exforge from the date launch

[22] The documents Plaintiffs seek are a narrowly tailored subset of those described in Subsection B, *infra*. *See also* Ex. 11, at 1-2.

planning began until April 1, 2015.

4. Documents sufficient to show the amount of generic Exforge finished product inventory that Lupin had on hand at the time of launch on March 30, 2015 and the date Lupin began to manufacture that inventory.

5. Lupin's generic Exforge launch timeline(s) showing planned and completed tasks in preparation for launch starting on January 1, 2011 and ending on April 1, 2015.

6. Documents sufficient to show when Lupin ordered the required active pharmaceutical ingredients ("API"), other excipients, and packaging intended for use in its first commercial batches of generic Exforge manufactured for its March 30, 2015 launch, and in what quantities.

7. Documents between January 1, 2011 and March 30, 2015 sufficient to show the extent to which, if at all, Lupin considered and took steps towards launching generic Exforge earlier than March 30, 2015. This may include launch timelines, purchases of API or other excipients, manufacturing of process validation batches, or internal correspondence indicating a proposed launch date.

8. Documents sufficient to show whether Lupin encountered any difficulties in manufacturing its commercial batches of generic Exforge in preparation for its March 30, 2015 launch.

9. Documents sufficient to show when Lupin purchased or made available the equipment used in the manufacturing of generic Exforge commercial batches in advance of its March 30, 2015 launch.

As explained below, the documents sought are (1) relevant to Plaintiffs' causation case, (2) not unduly burdensome to produce, and (3) similar to what Lupin was ordered to produce in another case in this District. Moreover, the nine categories of documents are described with particularity and cover a narrow time period: some span a four-year period, while others – such as process validation reports and finished product inventory prior to launch – span only several months.

A. The Agreed-Upon Documents Sought By Plaintiffs Are Relevant to the Underlying Litigation

One of the central questions in this case is whether, had Par launched earlier absent Novartis' payment for delay, Lupin and other generic manufacturers would have likewise been, ready, willing, and able to market generic Exforge earlier than March 2015, when Par's 180-day

exclusivity period ended. In other delayed-generic antitrust cases, courts have recognized that evidence of when other generic filers would have been ready, willing, and able to market their generic products was relevant to issues of, without limitation, causation and damages. *See, e.g., In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 169-72 (S.D.N.Y. 2018) ("*Namenda I*"); *In re Neurontin Antitrust Litig.*, No. 02-1390 FSH, 2013 WL 4042460, at *10 (D.N.J. Aug. 8, 2013) (defendant unsuccessfully argued at summary judgment that "Plaintiffs cannot establish that any alleged antitrust misconduct caused their injury because" generic manufacturer "did not obtain FDA approval" in time); *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-civ-7488 (CM) (JCF), 2017 WL 3822883, at *5 (S.D.N.Y. Aug. 30, 2017) ("*Namenda II*") (documents sought are "integral to a meaningful understanding of the company's efforts to launch the product").

It is well understood that the greater the number of generic competitors, the lower the prices purchasers of pharmaceutical products will pay.[23] The more generics that could and would have entered the market earlier but for the alleged anticompetitive agreements, the larger the damages incurred by purchasers such as the Plaintiffs. Documents responsive to Plaintiffs' Request Nos. 4 and 5 would demonstrate that Lupin could have come to market earlier in the absence of anticompetitive conduct and, thus, that Defendants' agreement significantly inflated the prices paid by purchasers of amlodipine/valsartan tablets.

[23] *See, e.g., In re Intuniv Antitrust Litigation*, No. 1:16-cv-12653-ADB, 2019 WL 4645502 at *10 (D. Mass. Sept. 24, 2019). *See also* Henry G. Grabowski et al, *Evolving Brand-Name And Generic Drug Competition May Warrant A Revision of the Hatch-Waxman Act*, 30:11 Health Affairs, 2157, 2158 (Nov. 2011) (summarizing economic studies on brand and generic pharmaceutical competition and observing that "[f]irst, more generic versions of a drug generally led to greater generic price discounts and higher market share for the generic versions collectively."); Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, ii-iii, 33, 46, 48 (2011) (finding that average price of a generic drug falls with an authorized generic on the market during 180 day exclusivity); Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 790, 797 (2007) (same); David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics*, 87 The Review of Economics and Statistics 37, 43-44 (2005) (finding that generic price discount increased when a second generic entered the market, and increased further when the third generic entered the market).

Tellingly, Lupin has not claimed otherwise or argued that the requested documents are not relevant.

B. Production of the Agreed-Upon Documents Is Not Unduly Burdensome.

An objecting party that claims requested discovery is too burdensome must show evidence of the burden. *See, e.g., Aristocrat Leisure Ltd. v. Deutsche Bank Tr. Co. Ams.*, 262 F.R.D. 293, 300 (S.D.N.Y. 2009) (arguments of undue burden require the submission of an affidavit "describing the burden."); *Bridgeport Music, Inc.*, 2007 WL 4410405 at *1-2; *MacNamara*, 2006 WL 3298911, at *15; Fed. R. Civ. P. 26(b)(2)(C)(iii). While Rule 45 places an obligation on Plaintiffs to take "*reasonable* steps to avoid imposing undue burden or expense on a person subject to the subpoena,"[24] "undue burden" arguments should be rejected where the third-party subpoena target may be the only source of the information sought, and where that information is relevant to the central issues in the case. *See In re Namenda Direct Purchaser Antitrust Litigation*, No. 15-Civ-7488, 2017 WL 4700367, at *3 (S.D.N.Y. Oct. 19, 2017) (finding non-party's undue burden "arguments are unpersuasive. While the money and time that will be spent on the production is not trifling, it is small in comparison with the potential damages in this case."); *Amphenol Corporation v. Fractus, S.A.*, 19 Misc. 160 (PAE), 2019 WL 2521300, at *5-6 (S.D.N.Y. June 19, 2019); *A & R Body Specialty & Collision Works, Inc. v. Progressive Cas. Ins. Co.*, No. 3:07-CV-929-WWE, 2013 WL 6044333, at *12 (D. Conn. Nov. 14, 2013) (rejecting subpoena target's undue burden arguments). Additionally, a non-party is typically required to absorb the costs of complying with a subpoena *duces tecum*. *See* Fed. R. Civ. P. 45(c)(2)(B) advisory committee's notes to 1991 amendment; *Florida Software Sys., Inc. v. Columbia/HCA Healthcare Corp.*, No. 99-MC-0036-E, 2002 WL 1020777, at *4 (W.D.N.Y. Feb. 25, 2002), *order vacated in part*, No. 99-MC-0036E,

[24] Fed. R. Civ. P. 45(d)(1) (emphasis added).

2002 WL 31011885 (W.D.N.Y. Aug. 9, 2002) ("Generally, reimbursement only occurs where the costs are great or the document demand unreasonably broad."). Lupin has not argued burden and for good reason: Lupin cannot show that producing the documents sought by this Motion would be unduly burdensome.

First, Lupin is not lacking in resources, and is the only source from which Plaintiffs can obtain the documents sought. As a large, sophisticated pharmaceutical company regularly engaged in generic drug development in a highly regulated industry (including FDA record-keeping requirements) and related litigation, compliance with subpoenas and discovery requests is a natural course of business – and Lupin is represented by experienced regulatory and antitrust counsel. After repeated discussions and negotiations, Plaintiffs agreed to a narrow set of documents responsive to Requests 4 and 5 that balance the relevant timeframe, the physical locations and facilities at issue, Plaintiffs' need for the documents, and any burden on Lupin.[25]

Second, Plaintiffs' Subpoena was narrowly tailored to seek relevant documents, which Plaintiffs' counsel identified based on our extensive experience litigating similar pharmaceutical antitrust cases over many years. Plaintiffs' Subpoena Request Nos. 4 and 5 initially sought:

> 4. All documents concerning Your, Par's, Novartis's or any other company's actual, proposed, or contemplated plans for launching Generic Exforge or Generic Exforge HCT, including the following: (i) launch timelines, new product launch meeting minutes, projections, and forecasts, including any assumptions used; (ii) schedules; (iii) launch updates, action items from new product launch meetings, and launch team meeting minutes; (iv) "at-risk" launch analyses and discussions; (v) manufacturing forecasts; (vi) sourcing of active and inactive ingredients (including communications with any suppliers); (vii) exhibit batches, scale up, validation, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same; and (viii) public statements (including statements to investors or courts) and competitive intelligence.

[25] *See* Section III, *supra*.

> 5. All documents concerning any regulatory, legal, technical, manufacturing, or other issues or reasons why You or any other Generic Exforge ANDA filer could or could not or would or would not commercially launch a Generic version of Exforge prior to September 30, 2014, including but not limited to:
>
> a. All documents concerning the manufacturing sites, facilities, equipment, and other resources proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing, and launch of Generic Exforge;
>
> b. All documents concerning CGMP, inspections, manufacturing, quality control, or quality assurance regarding any manufacturing sites, facilities, or equipment proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing, and launch of Generic Exforge;
>
> c. All documents relating to potential or actual suppliers of active and inactive ingredients, container/closure systems, labeling, tooling, or other vendors of products or services for Generic Exforge, including, but not limited to, communications with any such company(ies); orders and cancellation of orders; invoices and payments; contracts (including amendments and supplements thereto); drafts of contracts; compliance with contracts; disputes; settlements of disputes; forecasts; projections; manufacturing ability; supply requirements; production schedules; supply schedules; product marketing; product launch dates internal memoranda; emails; meeting agendas and minutes; transcripts of conversations; and drug master files;
>
> d. All documents relating to actual and theoretical manufacturing capacity and the rate limiters on that capacity, including any shortages in raw materials, manufacturing sites and/or equipment, or other rate limiters for Your Generic Exforge product;
>
> e. Documents sufficient to show the amount of inventory expressed in terms of weeks or months on hand of inventory that You had of Generic Exforge at the time of anticipated launch and/or at the time You actually launched Your Generic Exforge product;
>
> f. Documents sufficient to show batch sizes, manufacturing process, throughput times per batch, and manufacturing rates for Your Generic Exforge product.[26]

Third, these requests were narrowed during the negotiation process with Lupin, such that, in response to Request No. 4, Plaintiffs agreed to seek "New Product Launch Meeting Minutes, …

[26] Ex. 1, at 8-10.

launch timelines, projections, and forecasts, schedules, launch updates and launch team meeting minutes, manufacturing forecasts, records of exhibit batches, scale up batches, validation batches, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same."[27] In response to Request No. 5, Plaintiffs agreed to seek "documents sufficient to show any regulatory, legal, technical, manufacturing, or other issues or reasons why Lupin could or could not or would or would not commercially launch generic Exforge prior to September 30, 2014."[28] As Plaintiffs explained in Section V(A), *supra*, the documents sought are relevant to Plaintiffs' causation case, as they go to whether Lupin could have been, ready, willing, and able to market generic Exforge earlier than March 2015.

Fourth, any generic pharmaceutical company intending to market or marketing a product in the United States is statutorily required to maintain its process validation documents in a readily accessible manner in the event FDA desires to review them to confirm compliance with FDA Current Good Manufacturing Practices ("CGMPs"),[29] therefore, any burden Lupin may claim regarding having to spend time and effort to locate its process validation records is actually minimal and consistent with the standard production obligations imposed on non-parties. *See Kenyon v. Simon & Schuster, Inc.*, 2016 WL 5930265, at *5 (S.D.N.Y. Oct. 11, 2016) (finding that "[w]hat [Lupin] describes as an undue burden" – document collection and review from its files – "is merely the typical process for a corporation responding to document requests," and rejecting notion that "that even the normal burden of document production is too much for a nonparty"). Indeed, Lupin's production of a process validation report for its generic Exforge HCTZ product

[27] *See* Ex. 2, Apr. 19, 2019 Correspondence from Lupin to Pls., at 1.

[28] *Id*.

[29] *See* 21 U.S.C. § 355(k)(2). *See also*, "Facts About the Current Good Manufacturing Practices (CGMPs)," https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm.

confirms this. Additionally, as explained *supra*, the agreement with Lupin further narrowed the scope of the documents Plaintiffs seek, and Lupin has offered no specific reasons why compliance with its agreement would be burdensome. *Cf. Namenda II* 2017 WL 3822883, at *6 (S.D.N.Y. Aug. 30, 2017) ("Lupin Pharmaceuticals next argues that searching for and producing further documents from its own files would be unduly burdensome. But the showing is anemic. . . . And, as the plaintiffs point out, the company has failed to support its burden argument by, for example, 'detailing the volume of documents at issue or the number of personnel hours that would be necessary to produce the [requested] documents.'"). Consequently, Lupin is the only source for the documents Plaintiffs seek, not only possesses the knowledge, time, and financial resources to comply with this subpoena, but may also readily have an accessible source for documents responsive to the subpoena.[30]

C. The Discovery Sought by Plaintiffs Is Consistent with Discovery Lupin Has Been Ordered to Produce in a Similar Case in This District.

Lupin has admitted that the documents sought by Plaintiffs are the "same types of documents that Plaintiffs sought from Lupin Pharmaceuticals, Inc. in response to a third-party subpoena issued in *In re Namenda Direct Purchaser Antitrust Litigation*."[31] The facts in *Namenda* are nearly identical to this case: Lupin made an agreement in that "pay-for-delay" antitrust case to produce similar documents,[32] then refused to comply until it was faced with motion practice. *See*,

[30] *See Papanicolas v. Project Execution & Control Consulting, LLC*, No. CIV. A. CBD-12-1579, 2015 WL 1242755, at *2-3 (D. Md. Mar. 17, 2015).

[31] Ex. 2, April 19, 2019 Correspondence from Lupin to Pls., at 2.

[32] Documents missing from Lupin's production in the *Namenda* case included "documents sufficient to show the following: (1) when Lupin Pharmaceuticals began preparations for real world launch of its generic Namenda product; (2) when or where validation batches were made; (3) when the first commercial batches were manufactured; (4) when the commercial batches needed for launch were fully manufactured; (5) the quantity Lupin Pharmaceuticals estimated it would have to produce for launch; and (6) communications from project managers concerning preparation for launch, launch meetings, or spreadsheets tracking what batches were manufactured." *Namenda II*, 2017 WL 3822883, at *2 (S.D.N.Y. Aug. 30, 2017).

e.g., *Namenda II* 2017 WL 3822883, at *2 (S.D.N.Y. Aug. 30, 2017) ("Lupin Pharmaceuticals ultimately agreed to produce 'high level documents sufficient to show Lupin's plans to scale-up, manufacture, and/or market Namenda IR that are prepared by Lupin's Commercial Department.' At the beginning of July 2017, immediately after Lupin Pharmaceuticals completed production pursuant to the agreement, the plaintiffs objected that responsive documents were missing. . . .") (internal citations omitted); *id.* at *5 ("To the extent that Lupin Pharmaceuticals argues that the categories of documents the plaintiffs have identified are 'outside of the [a]greement,' I reject that contention. Those categories appear relevant to the company's preparation to launch its generic memantine product, and Lupin Pharmaceuticals has not provided any evidence that they were excluded from the agreement's coverage.") (internal citations omitted).

The *Namenda II* court considered Lupin's superficial production, and then rejected Lupin's unilateral renunciation of its agreed discovery obligations:

> Lupin Pharmaceuticals focuses on its promise to produce documents "sufficient to show" its efforts to launch the generic drug, asserting that it produced documents "including forecasts, launch calendars, and ANDA-related filings." But according to the plaintiffs, the production is devoid of documents showing (1) the date process validation began, (2) the date process validation ended (and whether the first attempt at process validation was successful), (3) the date Lupin ordered API in preparation for launch, (4) the date Lupin received its API, (5) the date Lupin began manufacturing scale-up batches in advance of its July 11, 2015 launch, (6) the date Lupin completed manufacture of scale-up batches, (7) how many commercial batches (and what was the batch size) Lupin had successfully manufactured prior to July 11, 2015, and (8) whether Lupin experienced any difficulty in manufacturing scale-up batches. Again, these facts would seem to be included within the agreement; indeed, they are integral to a meaningful understanding of the company's efforts to launch the product. . . . It thus appears that the company has not yet produced documents "sufficient to show" its launch plans.

Id. at *5 (record citations omitted).

Plaintiffs seek similar documents in this case, consistent with the needs of this case, the agreement with Lupin on the scope of the Subpoena, and the precedent set in *Namenda II*. This

Court, like the *Namenda II* court, should order Lupin to comply with its discovery obligations and promptly produce the documents it agreed to produce almost a year ago. *See id.* at *10 (granting the motion to compel against Lupin).

VI. CONCLUSION

For the reasons stated herein, Plaintiffs respectfully move the Court to compel Lupin to fulfill its outstanding discovery obligations under its agreement with Plaintiffs, including full compliance with the narrowed Request Nos. 4-5, as outlined herein.

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Respectfully Submitted,

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